UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/568,392 | 02/15/2006 | Hisakazu Mihara | SAE0038 | 1013 |

23353 7590 09/16/2008

RADER FISHMAN & GRAUER PLLC
LION BUILDING
1233 20TH STREET N.W., SUITE 501
WASHINGTON, DC 20036

| EXAMINER | |
|---|---|
| WANG, CHANG YU | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1649 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 09/16/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/568,392 | MIHARA ET AL. | |
| | Examiner | Art Unit | |
| | Chang-Yu Wang | 1649 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *5/30/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *4-6 and 11-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7-10 and 15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/15/06,6/30/06,1/4/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

***Sequence compliance***

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825. Specifically, a same sequence identification. SEQ ID NO:1 has been used for different amino acid sequences presented on p. 11 and 15 of the instant specification. In case these sequences are new, Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences that are present in the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO: ) be made in the specification and claims wherever a reference is made to that sequence. See M.P.E.P. 2422.04.

The text of the instant specification is not in compliance with the requirements for Sequence Identifiers (see MPEP 2422.03). The sequences listed on p.11 and p.15 are different sequences but are recited as SEQ ID NO:1. These sequences are different thus they need different sequence identifiers. Appropriate correction is required.

***Status of Application/Election/Restrictions***

2. Applicant's election without traverse of Group I (claims 1-3, 7-10 and 15-19) in the reply filed on 5/30/08 is acknowledged.

Claims 1-19 are pending. Claims 4-6 and 11-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/30/08. Claims 1-3, 7-10 and 15-19 are under examination in this office action.

***Specification***

3. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

**Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.

(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

4. The specification filed 5/11/07 is objected to because Applicant fails to indicate what part of the specification was amended or modified (i.e. insertion should be underlined and deletion should be strikethrough). In addition, the format of word spacing in the specification is not proper; therefore, it is difficult to distinguish each word individually. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, and 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, and 7-10 are indefinite because the claims recite "14 to 23 residues of amyloid-b-peptide" without a reference to a precise amino acid sequence identified by a proper SEQ ID NO:. It is not clear what is encompassed within the limitation of "14 to 23 residues of amyloid-b-peptide". It is not clear which 14 to 23 residues of amyloid-b-peptide Applicant intended to include. There is no limitation on what would or would not be included in such a peptide and thus would be within the scope of the claims.

In addition, the recitation "derived from" in the claims makes claims indefinite because the claims and the disclosure fail to set forth the metes and bounds of what is encompassed within the definition of a peptide "derived from...".

***Claim Rejections - 35 USC § 101***

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 7-10 and 15-19 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" use for the claimed invention. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966):

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.

In this case, the claimed reagent has no specific and substantial utility. The instant claims 1-3, 7-10 and 15-19 are drawn to a reagent for amplifying the amyloid fibrosis of amyloid β-protein. The specification shows that artificial peptides named 10-4F and 10-3L can form amylod fibris and also increase fluorescent intensity in the presence of the nucleus (Aβ10-35) in a test tube. However, the instant application fails to disclose a specific biological significance of the claimed peptide or its use in the real

world. The claimed artificial peptides may be used to test whether its biochemical property in forming aggregation of Aβ10-35 in vitro or study the interaction between the claimed peptide and Aβ10-35 in vitro. But the instant specification fails to teach the relevance between the finding of enhanced aggregation of Aβ10-35 by the claimed peptide and diagnosis of AD.

First, it is not known why a person wants to use the claimed peptides to increase amyloid fibris in the brain since increasing amyloid fibris results in a more serious pathological condition. The specification fails to teach whether increasing amyloid fibris formation by the claimed peptides has any benefit in the human brain. Although amyloid fibris formation can be found in the brain of AD patients, the specification fails to teach what the relevance between the enhanced Aβ10-35 aggregation by the claimed peptides in vitro and the diagnosis of AD or any particular disease. In addition, the specification fails to teach how to use such peptides in diagnosis of Alzheimer's disease (AD) and also fails to teach whether the claimed peptide can really be used to diagnose a person and determine whether the person is suffering from AD or other disease. Thus, the claimed reagent has not specific and substantial utility.

The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. See Brenner v. Manson, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful

conclusion." A patent is therefore not a license to experiment. See also the Revised Interim Utility Guidelines available at www.uspto.gov.

The claimed invention also lacks a well-established utility. A well-established utility is a specific, substantial, and credible utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. Since the instant specification does not disclose a substantial "real world" use for the claimed reagent as set froth above, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 7-10 and 15-19 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. Claims 1-3, 7-10, 16 and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, were it enabling for artificial peptides 10-3F, 10-4F and 10-3L as defined by SEQ ID NO:1 wherein X is Phe and Y is Leu in SEQ ID NO:1 for 10-3F, wherein X is Leu and Y is Phe in SEQ ID NO:1 for 10-4F and wherein X is Leu and Y is

Leu in SEQ ID NO:1 for 10-3L for amplifying amyloid fibrosis, would still not reasonably provide enablement for structurally undefined peptides derived from Aβ (14-23) or undefined 14-23 residues of amyloid β-peptide with any substitution for amplifying amyloid fibrosis or diagnosis of AD as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in the scope with these claims.

"There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is 'undue'. These factors include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)". See MPEP § 2164.01.

**Breath of the claims:** Claims 1-3, and 7-10 are drawn to a reagent for amplifying the amyloid fibrosis of amyloid β-protein comprising a peptide consisting of 14 to 23 residues of amyloid-β-peptide or a peptide derived from the peptide by substituting all positively charged side-chain amino acids with Lys and substituting all negatively charged side-chain amino acids with Glu and optionally substituting all hydrophobic residues with Leu. The claims encompass a genus of functionally and structurally undefined variants of 14 to 23 residues of amyloid-β-peptide, which are not

supported by the specification. Claims 16 and 19 encompass peptides that are not enabling as described on p. 20 of the specification.

**Nature of the invention:** The instant invention is to characterize the biochemical property of several artificial peptides derived from amyloid-b peptide. The specification shows that artificial peptides named 10-3F, 10-4F and 10-3L as defined by SEQ ID NO:1 wherein X is Phe and Y is Leu for 10-3F, X is Leu and Y is Phe for 10-4F and X is Leu and Y is Leu for 10-3L can form amylod fibris and also increase fluorescent intensity in the presence of the nucleus (Aβ10-35) in a test tube. The specification also shows that a peptide named 10-3A as defined by SEQ ID NO:1 wherein X is Ala and Y is Leu in SEQ ID NO:1 did not show increased fluorescent intensity (p. 20 of the instant specification).

**State of the prior art/predictability/experimentation:** Based on the specification, Applicant is enabled for peptides 10-3F, 10-4F and 10-3L with defined sequences for forming amyloid fibris. However, the claims are not limited to the sequences as set forth above but also include structurally and functionally undefined variants of peptides consisting 14-23 of amyloid b-peptide with different substitutions. The instant specification provides insufficient guidance as to enable a skilled artisan to practice the claimed invention commensurate in scope with the claims without undue experimentation.

It is known in the art that a single amino acid change can abolish the binding ability or activity of a molecule. For example, a substitution of lysine residue by glutamic acid at position 118 of acidic fibroblast growth factor results in a substantial loss of its

biological activity including the binding ability to heparin and its receptor (Burgess et al. J of Cell Bio. 111:2129-2138, 1990). Although many amino acid substitutions are possible in any given protein, the position of where such amino acid substitutions can be made is critical for maintaining the function of a protein; i.e. only certain positions can tolerate conservative substitutions without changing the relationship of three dimensional structure and function of the protein (col 2, p. 1306, Bowie et al. Science, 1990, 247:1306-1310). Even if an active or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would not immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active because conformation is dependent upon surrounding residues; i.e. substitution of non-essential residues can often destroy activity. In addition to a core determinant sequence, the protein-protein interaction also relies on the flanking or noncontiguous residues (see p. 445 the second column, first paragraph, Pawson et al. 2003, Science 300:445-452). The optimal binding motif for a domain is not necessarily suitable for physiological or in vivo interaction. The predictive data always need to be validated by actual analyses in cells (see p. 445, the third column, second paragraph, Pawson et al. 2003, Science 300:445-452). Applicant fails to teach what specific structures/amino acid sequences can/cannot be included/changed in all claimed peptides in order to preserve the ability of forming amyloid fibris. In addition, claims 15 and 19 encompassed peptides that are not enabling because based on the specification, peptide 10-3A, which is defined as SEQ ID NO:1 wherein X is Ala and Y is Leu in SEQ ID NO:1 cannot form amyloid fibris (see p. 20 of the instant specification).

Thus, Applicant is not enabled for all peptides derived from amyloid-b-peptide with any substitution or any combination of substitutions.

In addition, claims 7-10 recite the claimed reagents for detection of disease attributable to amyloidosis or AD. However, the specification provides no working example as to how to detect AD or other diseases attributable to amyloidosis by using the claimed peptide. Thus, it is unpredictable whether the claimed peptide can be used to detect the claimed diseases without undue experimentation. Therefore, in view of the breath of the claims, the necessity of experimentation, the limited working examples, the unpredictability of the art, and the lack of sufficient guidance in the specification, undue experimentation would be required by a skilled artisan to perform in order to practice the claimed invention.

9. Claims 1-3 and 7-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics,

structure/function correlation, methods of making the claimed product, or any combination thereof.

Claims 1-3 and 7-10 are drawn to a reagent for amplifying the amyloid fibrosis of amyloid β-protein comprising a peptide consisting of 14 to 23 residues of amyloid-β-peptide or a peptide derived from the peptide by substituting all positively charged side-chain amino acids with Lys and substituting all negatively charged side-chain amino acids with Glu and optionally substituting all hydrophobic residues with Leu. The claims encompass a genus of functionally and structurally undefined variants of 14 to 23 residues of amyloid-b-peptide, which are not supported by the specification.

In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant is in possession of peptides 10-3F, 10-4F and 10-3L. However, the claims are not limited to the peptides as set forth above but also include structurally and functionally undefined variants of peptides consisting of 14-23 residues of amyloid-b-peptides. The specification only describes 10-3F, 10-4F and 10-3L for forming amyloid fibris. The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of functionally and structurally undefined variants of 14 to 23 residues of amyloid-b-peptide. There is no description of the conserved regions which are critical to the function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to

function. Structural features that can distinguish the variant peptides with all possible substitutions in the genus from other peptides are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the peptides encompassed: there is no guidance in the art as to what the defining characteristics of the claimed variants with all possible substitutions might be. Since the common characteristics/features of the claimed variants are unknown, a skilled artisan cannot envison the functional correlations of the genus with the claimed invention. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the genus of proteins.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The

compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, the claimed reagents have not met the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 7 are rejected under 35 U.S.C. 102 (b) as being anticipated by Tjernberg et al (J. Biol. Chem. 1999. 274:12619-12625 as in IDS).

Claims 1 and 7 are directed to a reagent for amplifying the amyloid fibrosis of amyloid b-protein or detection diseases attributable to amyloidosis comprising a peptide consisting of 14-23 residues of amyloid β-peptide or a peptide derived from the peptide by substituting all positively charged side-chain amino acids with Lys and substituting all

negatively charged side-chain amino acids with Glu. Although the limitation of "a peptide consisting of 14-23 residues of amyloid b-peptide" is indefinite, the examiner interprets the limitation as a peptide consisting of amino acids at position 14 to 23 of Aβ1-42, which is regularly named Aβ14-23.

Tjernberg et al. teach a reagent for polymerization of the amyloid β peptide consisting of Aβ14-23, which meets the limitation of a peptide consisting of 14-23 residues of amyloid β-peptide as recited in instant claims 1 and 7 (see p. 12622, 2nd col., 2nd paragraph). The intended use of amplifying the amyloid fibrosis of amyloid-β protein is identical to the concept of polymerization of the amyloid β peptide. In addition, the intended use of amplifying the amyloid fibrosis of amyloid b-protein and detection of diseases attributable to amyloidosis is not given patentable weight because the prior art structure of the product is identical and is capable of performing the intended use, then it meets the claim. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Therefore, Claims 1 and 7 are anticipated by Tjernberg et al..

***Conclusion***

11. NO CLAIM IS ALLOWED.

12. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday from 8:30 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/
Chang-Yu Wang, Ph.D.
September 9, 2008

/Christine J Saoud/
Primary Examiner, Art Unit 1647